

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0153]

9508 '01 APR 11 A8:01

DMB

Display Date	4-12-01
Publication Date	4-13-01
Certifier	<i>MB</i>

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Registration of Cosmetic Product Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the voluntary registration of cosmetic product establishments with FDA.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

N I

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Voluntary Registration of Cosmetic Product Establishments—21 CFR Part 710 (OMB Control Number 0910–0027)—Extension

Under the Federal Food, Drug, and Cosmetic Act (the act), cosmetic products that are adulterated under section 601 of the act (21 U.S.C. 361) or misbranded under section 602 of the act (21 U.S.C. 362) may not be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, FDA requests that establishments that manufacture or package cosmetic products register with the agency on Form FDA 2511 entitled “Registration of

Cosmetic Product Establishment.” Regulations providing procedures for the voluntary registration of cosmetic product establishments are found in 21 CFR part 710.

Since mandatory registration of cosmetic establishments is not authorized by statute, voluntary registration provides FDA with the best information available about the location, business trade names used, and the type of activity (manufacturing or packaging) of cosmetic product establishments that participate in this program. In addition, the registration information is an essential part of planning onsite inspections to determine the scope and extent of noncompliance with applicable provisions of the act. The registration information is used to estimate the size of the cosmetic industry regulated. Registration is permanent, although FDA requests that firms submit an amended registration on Form FDA 2511 if any of the information originally submitted changes.

FDA uses registration information as input for a computer data base of cosmetic product establishments. This data base is used for mailing lists to distribute regulatory information or to invite firms to participate in workshops on topics in which they may be interested.

FDA estimates the burden of this collection of information as follows:

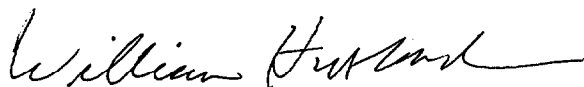
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
710	FDA 2511	50	1	50	0.4	20

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

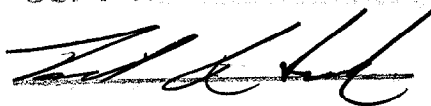
The burden estimates are based on past experience and on discussions with registrants during routine communications. FDA receives an average of 50 registration submissions annually. There has been no change over the past 16 years in the number of submissions of Form FDA 2511 or in the time it takes to complete this form.

Dated: 4/6/01
April 6, 2001.



William K. Hubbard,
Senior Associate Commissioner for
Policy, Planning, and Legislation.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL



[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-S